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Laparoscopic adjustable gastric banding for clinically severe (morbid) obesity

Wendy L. Schneider

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This Health Technology Report has been prepared on the basis of available information of which the Foundation is aware from public literature and expert opinion and attempts to be current to the date of publication. It has been externally reviewed. Additional information and comments relative to the report are welcome and should be sent to:

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SUMMARY

- All studies critically reviewed for this assessment reported outcomes such as decreases in BMI, weight loss and/or excess weight loss after laparoscopic adjustable gastric banding (LAGB) surgery.
- Another recently released technology assessment concluded that

  "the safety and/or efficacy of the LAGB procedure cannot be determined at the present time due to an incomplete and/or poor quality evidence-base. It is recommended that further research be conducted to establish safety and/or efficacy".

- Complications specific to adjustable gastric bands include; band slippage, gastric perforation, twisted reservoir, pouch dilation, leaking bands and infection of access port. Re-operation was required in approximately 4% of cases due to one or more of these complications. Of note is the range of time over which complications occurred; 3 months to 3 years.
- The laparoscopic adjustable band is approved for use in Canada but not in the United States.
- Whether LAGB surgery will replace current standard of care (Roux-en-Y gastric bypass) or become part of mainstream treatment for morbid obesity can only be determined by well designed studies reporting greater than five year outcomes of patients who have had the procedure.
- Future research into the efficacy and safety of LAGB surgery should address whether a subgroup of morbidly obese patients can be identified in whom this method could be employed as an alternative to standard of care. Studies should also include outcomes such as weight loss, improvement in co-morbidity and quality of life assessment.

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INTRODUCTION

In Canada approximately 50% of adults are overweight and one in six is obese [15, 16, 28]. One third of these Canadians are at increased risk of disability, disease and early death because of being obese [8]. Severity of obesity (clinically severe obesity and morbid obesity are used interchangeably in the context of this report) is measured using the Body Mass Index (BMI). It is calculated by taking a person's weight (in kilograms) and dividing it by their height (in meters) raised to the power of two:

$$BMI = Weight / Height^2$$

A BMI of greater than 35 kg/m^2 with attendant co-morbidities, being 45 kilograms overweight, or a BMI that exceeds 40 kg/m^2 are criteria used to define clinically severe obesity [3, 7, 15, 16, 26]. The types of morbidity encountered in the clinically severe obese population are diabetes, hyperlipidemia, hypertension and pulmonary insufficiency, debilitating arthritis of weight-bearing joints and others.

Bariatric surgery methods to treat clinically severe obesity have evolved from the jejuno-ileal bypass of twenty years ago to the current standard of care; Roux-en-Y gastric bypass [4, 13, 24]. Bariatric surgeries that are strictly 'restrictive' in nature are the vertical banded gastroplasty (stomach stapling), non-adjustable (fixed) gastric banding, and adjustable gastric banding. In the latter two surgeries a gastric band divides the stomach into two chambers such that a small outlet is accommodated between them. Having a smaller (upper) stomach permits the patient to consume only small quantities of food at a time. Non-adjustable gastric bands do not allow for variation in outlet size to achieve an optimal opening between the upper and lower stomach. The adjustable band was developed to allow for modification of the opening [2, 21, 22, 37]. Adjustable bands were first placed via laparotomy (open surgery) in order to allow surgeons to familiarize themselves with the device and to assess outcomes using an adjustable as compared to a fixed band. However, the adjustable band can be placed laparoscopically allowing surgical treatment for those clinically severe obese patients who might otherwise not be eligible.

A request for information about the use of laparoscopic adjustable gastric banding for clinically severe obese patients was received from Alberta Health & Wellness. This report will highlight evidence from published scientific literature regarding the safety, efficacy and effectiveness of the laparoscopic adjustable gastric band (LAGB) procedure. Issues of training, patient selection criteria and post-operative patient care will be outlined. Data provided in this report is intended to inform a decision whether LAGB surgery can safely be performed in this patient population outside a hospital setting.

The methodology used in the preparation of this report is outlined in Appendix A. Only clinical studies were considered.

Description of the technology

LAGB surgery involves laparoscopically placing an adjustable band around the upper part of the stomach such that the stomach is partitioned into two sections. The band is tightened creating an outlet ('stoma') between the tiny upper and large lower stomach. The capacity of the upper segment of the stomach ranges between 10 and 15 mL. The adjustability of the band allows the surgeon to alter the diameter of the stoma. The adjustable gastric band has an inflatable tube incorporated in it that is connected to a port anchored to the rectus abdominus muscle. The adjustable band is not inflated until at least 4 weeks after surgery in order to allow it to get anchored in position by fibrous tissue (Deitel, personal communication). Once anchored, if the patient is not losing weight then saline is injected percutaneously through the skin into the port, which in turn decreases the volume of the upper stomach by constricting the band [36]. If the patient is losing weight too quickly the band is loosened by withdrawing saline allowing for a larger outlet [7, 14, 30]. The band itself can be coated with silicone or other types of materials impregnated with silicone [2, 10, 14, 30, 36].

Regulatory considerations

There is more than one manufacturer of adjustable gastric bands. However, the regulatory considerations mentioned here address the band that is available in North America.

In Canada all medical devices imported or sold are required to have a medical device license issued by Health Canada. In addition, the device must be classified according to the Medical Devices Regulations that became effective July 1, 1998. The laparoscopic band (Lap-band®) used in obesity surgery is classified as a Class III as it is 'intended to remain in the body for at least 30 consecutive days'. The Therapeutic Products Program of Health Canada issued the medical device license for the Lap-band® on September 20, 1999 (Health Canada, personal communication).

The Gastroenterology and Urology Devices Panel of the United States Food and Drug Administration met to formally consider and make a recommendation on the pre-market approval application for the Lap-Band Adjustable Gastric Banding System (BioEnteric Corporation) [25]. The Panel voted 6 to 4 for disapproval of the Lap-Band based on a lack of adequate pre-market follow-up data for the 3-year period following implantation [35]. Currently there are no other adjustable gastric banding devices approved by the FDA for use in obesity surgery (US FDA, personal communication).

Evidence of efficacy and effectiveness

A systematic literature review entitled *Laparoscopic Adjustable Gastric Banding for the Treatment of Obesity* has recently been released by the Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S). Their objective was to assess the literature regarding the LAGB procedure for the treatment of obesity and make recommendations on the safety and efficacy of the technique. The Review Group stated that:

> "the safety and/or efficacy of the procedure cannot be determined at the present time due to an incomplete and/or poor quality evidence-base. It is recommended that further research be conducted to establish safety and/or efficacy" [9].

The nine studies critically reviewed for this report (one RCT, two prospective comparative studies, six clinical series), are summarized in Table 1. They reported outcomes of LAGB surgery for clinically severe obese patients [1, 12, 14, 17, 19, 24, 30, 32, 37]. Guidelines set out by the American Society for Bariatric Surgery (see Appendix B) were used in the analysis of the studies.

In Table 1, under 'post-operative complications', there are two terms used: conversion and re-operation. ***'Conversion'*** surgery occurs when the surgeon begins to laparoscopically insert the adjustable gastric band but has to 'convert' to open surgery due to the patient's liver lobe hypertrophy, short instruments, or incorrect band placement [10]. Eight of the ten studies highlighted in Table 1 reported conversion rates from one to 25%.

'Re-operation' results when there are complications after adjustable gastric band surgery, whether the band is placed by open or laparoscopic surgery. In general, there was a high incidence of re-operation due to complications such as band slippage, prolapse of the stomach through the band, rupturing of tubing, reflux disease and others [1, 14, 19, 20, 32]. All of the studies state that long-term follow-up is a necessary requirement of adjustable gastric banding surgery.

The Bariatric Analysis and Reporting Outcome System (BAROS) developed by Oria and Moorehead [34] allows for comparisons between studies of obesity surgery. Using a scoring table, points are added or subtracted while evaluating three main areas; percentage of excess weight loss, changes in medical conditions, and assessment of quality of life. Points are deducted if there are complications and/or re-operation. Two of the studies outlined in Table 1 [17, 24] used the BAROS in their outcomes evaluations.

Table 1: Studies of laparoscopic adjustable gastric band surgery

Author(s) Year/Study duration Type of publication Objectives Follow-up period	Number of patients (n) Characteristics of participants BMI and/or weight (kg)	Surgery duration Hospital stay (days) Post-operative Complications	Study outcomes	Study comments
Hell et al. [24] 2000 Jan '95 to Dec '95 (inferred from paper) Prospective comparative study, consecutive cases. To compare effects and outcomes of three different bariatric procedures (vertical banded gastroplasty, LAGB, Roux-en-Y gastric bypass) performed in two centres (USA and Austria) Follow-up: Roux-en-Y: 60 ±8.2 mo VBG: 40.1 ±8.3 mo LAGB: 39.7 ±7.6 mo	VBG: n=30 LAGB: n=30 Roux-en-Y: n=30 Stratification was performed for BMI, sex and age **VBG Group** Age: 35.1 ± 6.2 y BMI: 46.9 ± 9.9 kg/m^2 Weight: 139 ± 33.3 **LAGB Group** Age: 36.4 ± 4.8 y BMI: 46.9 ± 7.8 kg/m^2 Weight: 133 ± 22.7 **Roux-en-Y Group** Age: 41.26 ± 5.9 y BMI: 45.18 ± 8.2 kg/m^2 Weight: 135.74 ± 23.9	Surgery duration VBG: ⊼ 48 min LAGB: ⊼ 88 min Roux-en-Y: ⊼ 135 min Lengths of hospital stay not reported. No unusual perioperative or long-term complications have been observed in the three series.	Results are reported as excess weight loss (EWL) and with the BAROS evaluating system. **VBG** 0-24%EWL: 1 25-49% EWL: 12 50-74% EWL: 15 75-100% EWL: 2 BAROS score: 6.13 (very good) **LAGB** 0-24%EWL: 1 25-49% EWL:13 50-74% EWL: 15 75-100% EWL: 1 BAROS score: 5.99 (very good) **Roux-en-Y** 0-24%EWL: 0 25-49% EWL:2 50-74% EWL:6 75-100% EWL:22 ψ BAROS score: 7.15 (excellent) ψDifference between the Roux-en-Y EWL compared with VBG and LAGB was statistically significant	The outcomes of this study (EWL and BAROS score) favour the Roux-en-Y gastric bypass for the treatment of morbid obesity. Fair level of scientific evidence *, ideal follow-up.

Table 1 Studies of laparoscopic adjustable gastric band surgery (cont'd)

Author(s) Year/Study duration Type of publication Objectives Follow-up period	Number of patients (n) Characteristics of participants BMI and/or weight (kg)	Surgery duration Hospital stay (days) Post-operative Complications	Study outcomes	Study comments
De Wit et al. [12] 1999 Nov '95 – Feb '97 RCT To compare the efficacy of laparoscopic versus open adjustable silicone gastric banding procedures. Follow-up performed by a gastroenterologist at: 1, 4, 8, 11, 16, 20, 24, 36 and 52 wks After 1 y, one patient (Group 2) lost to follow-up.	Group 1 (Lap): n=25 Group 2 (Open): n=25 Included if had: History of obesity >5 y BMI > 40 kg/m^2 Documented past weight loss attempts Good motivation for surgery Age range: 18 to 55 y Excluded due to: Previous gastric surgery Large hiatal hernia Alcohol abuse Pregnancy Psychiatric disease/treatment Hormonal or genetic obesity-related diseases High risk associated with anesthesia Group 1: BMI: x̄ 51.3 ± 10.4 kg/m^2 Weight: x̄ 152.2 ± 31.4 Group 2: BMI: x̄ 49.7 ± 5.6 kg/m^2 Weight: x̄ 146.4 ± 19.9	Surgery duration: Group 1: x̄ 150 ± 48 min Group 2: x̄ 76 ± 20 min Hospital Stay: Group 1: x̄ 5.9 d (range: 4-10) Group 2: x̄ 7.2 d (range: 5-13) **Group 1** Patients who underwent conversion: 2 (inability to obtain pneumo-peritoneum) Cholecystectomy:2 Pulmonary: 2 Urinary infection: 2 **Group 2** Cholecystectomy (asymptomatic stone disease): 5 Pulmonary: 2 Fever: 2 There were no significant differences in early post-operative complications between the open and laparoscopic procedures.	There were no deaths. There were no significant differences in weight loss or change in BMI between the two groups. **Group 1** BMI: x̄ 39.7 ± 8.7 kg/m^2 Weight: x̄ 117.2 ± 25.2 kg Weight loss: x̄ 35 kg **Group 2** BMI: x̄ 39.1 ± 8.2 kg/m^2 Weight: x̄ 112.0 ± 19.1 kg Weight loss: x̄ 34.4 kg Re-admissions and overall hospital stay were significantly higher for Group 2.	Authors state that this study demonstrates that both laparoscopic and open adjustable silicone gastric banding can be performed safely as a treatment for morbid obesity. Therefore, laparoscopy is the preferred approach in morbidly obese patients undergoing adjustable silicone gastric band surgery. Good level of scientific evidence, short follow-up.

Table 1 Studies of laparoscopic adjustable gastric band surgery (cont'd)

Author(s) Year/Study duration Type of publication Objectives Follow-up period	Number of patients (n) Characteristics of participants BMI and/or weight (kg)	Surgery duration Hospital stay (days) Post-operative Complications	Study outcomes	Study comments
Doherty et al. [14] 1999. Prospective clinical series Cohort 1:Mar '92-May '95 Cohort 2: Jun '95-Jan '97 Ongoing comparative prospective investigation of open versus laparoscopic surgery using two different adjustable silicone gastric banding devices. Goal of the investigation is to evaluate the achievement of sustained weight loss without the need for re-op. Follow-up Cohort 1: $\bar{x}$ 58 mo (range 36 – 74 mo) Cohort 2: $\bar{x}$ 28 mo (range 16 – 35 mo)	Acceptance criteria for enrollment into the study: 45 kg overweight, failure to sustain weight loss with non-operative programs, no previous history of surgical treatment for obesity, age 18-51 y. All subjects were enrolled in a diet and behaviour modification program. **Cohort 1**: n=40 consecutive patients. Open placement of adjustable silicone gastric band. Age: $\bar{x}$ 34 y (19 – 51) BMI: $\bar{x}$ 50 kg/m^2 (39-75) Pre-op weight: $\bar{x}$ 147 (range 100 – 214) **Cohort 2**: n=22 consecutive patients. Lap placement of adjustable silicone lap-band (17), five patients were converted to open due to failed ASGB previously placed (2) and inadequate operative exposure (3). Age: $\bar{x}$ 33 y (19 – 43) BMI: $\bar{x}$ 47 kg/m^2 (37-73) Pre-op weight: $\bar{x}$ 143 (range 89 – 204)	Surgery duration/ hospital stay: not reported. No intra-operative complications. **Cohort 1:** Failures of the reservoir system occurred in 50% of the subjects, requiring re-op and/or replacement with an improved substitute. Intra-abdominal re-ops necessary in 40% of subjects. **Cohort 2:** Flipped or upside-down reservoirs: 3, (requiring re-op) Painful abdominal wall reservoirs: 2 Requested removal: 2 Herniation of the distal stomach causing band removal: 2	Comparisons were made only for patients who remained in the study with an intact band system. No mortality in either cohort. **Cohort 1:** Re-ops occurred due to obstructions, ineffective band, enlarged pouch with obstructive symptoms, or herniation of the distal stomach. BMI ($\bar{x}$): Decreased to a low of 2 y: 38 kg/m^2 3 y: 40.5 kg/m^2 (remained stable through the 3rd, 4th, and 5th y.) Weight ($\bar{x}$): 1 y: 113 kg 2 y: 111 kg 3 y: 117 kg 4 y: 117 kg 5 y: 116 kg **Cohort 2:** BMI decreased from ($\bar{x}$) 47 kg/m^2 to: 1 y: 40 kg/m^2 2 y: 42 kg/m^2 Weight ($\bar{x}$): 1 y: 118 kg 2 y: 127 kg	The need for major intra-abdominal re-op after ASGB remains unknown. Early experience shows the incidence is too frequent. Occurrence of complications was several months after surgery (range 21-55 mo). Addendum to the study: Five of 22 lap-band patients (23%) have required band removal. Fair level of scientific evidence. Ideal long-term follow-up in Cohort 1, good long-term follow-up in Cohort 2.

Table 1 Studies of laparoscopic adjustable gastric band surgery (cont'd)

Author(s) Year/Study duration Type of publication Objectives Follow-up period	Number of patients (n) Characteristics of participants BMI and/or weight (kg)	Surgery duration Hospital stay (days) Post-operative Complications	Study outcomes	Study comments
O'Brien, et al. [32] 1999 Jul '94 – Jan '98 Prospective clinical series To determine outcomes in patients treated by one surgeon, emphasizing the evolution of the technique, the early and later post-op problems, and the pattern of weight loss. Follow-up- 6 mo: n=199 1 y: n=120 18 mo: n=90 2 y: n=43 4 y: n=12	n=302 (Lap placement in 277, previous gastric stapling surgery was the main reason for an elective open approach in other patients). Eligibility: BMI >35 kg/m^2, suffering significant medical, physical or psychological disabilities and who had been attempting weight reduction by other means for at least 5 y. Age: x̄ 39 y (range 16-61) BMI: x̄ 44.5 kg/m^2 Weight: x̄ 124	Surgery duration: Initially 4 h As surgeon gained experience: 57 min (range 45-110) Hospital stay: (for the last 140 patients) 3.9 d (range 1-7) Conversion from lap to open surgery: 5 patients (insufficient exposure in 3, excessive bleeding in 1 and insufficient port length in 1). **Early post-op complications** Infection of reservoir site: 1 **Late post-op complications** Prolapse of stomach through the band: 27 (required re-op) Rupture of tubing: 6, (treated by reservoir replacement)	[Prolapse of the stomach appeared to be a significant post-op problem until a number of modifications of op and post-op technique were instituted. Overall frequency of band prolapse to date is 9%.] BMI: no data given Weight: no data given Authors report early gradual weight loss that progressed beyond 2 years. A formal review of co-morbidity has not yet been performed.	Authors state that it is too early to draw firm conclusions regarding effectiveness, however, the results do compare favourably with the outcomes of gastric bypass, and are better than those obtained (by these authors) with gastroplasty. Several years of additional follow-up are needed before optimal and durable weight loss is achieved. Poor level of scientific evidence. Several patients lost to follow-up.

Table 1 Studies of laparoscopic adjustable gastric band surgery (cont'd)

Author(s) Year/Study duration Type of publication Objectives Follow-up period	Number of patients (n) Characteristics of participants BMI and/or weight (kg)	Surgery duration Hospital stay (days) Post-operative Complications	Study outcomes	Study comments
Miller and Hell [30] 1999 Jul '94 – Aug '98 Prospective 4-y follow-up study. To assess all complications linked to two available gastric bands (adjustable silicone gastric band (ASGB) and Swedish adjustable gastric band (SAGB)). Follow-up: x̄ 28 mo (range 6 wks – 46 mo). Patients were seen once a mo for the first 3 mo, then every third month during the 1st y. Thereafter, patients were seen once every 6 mo for the first 2 y and finally once per y.	Total n=158 Follow-up available for 156 patients ASGB: n= 102 Age: x̄ 38 y (19-72) BMI: x̄ 45 kg/m^2 (38-65) Pre-op weight: x̄ 134 (range 92-215) SAGB: n=54 Age: x̄ 35 y (17-61) BMI: x̄ 43 kg/m^2 (37-68) Pre-op weight: x̄ 136 (range 89 – 230)	**Surgery duration** ASGB: not reported SAGB: not reported **Hospital stay** ASGB: 4.3 d SAGB: 3.3 d **Post-op complications** ASGB: 7 SAGB: 6 **Early post-op complications** (required re-op) Trocar wound hematoma: 1 (ASGB) Port wound infection: 1 (SAGB) **Late post-op complications** (required re-op) Pouch dilatations: 2 (ASGB) Band leaks: 3 (ASGB 2, SAGB 1) Band migration: 1 (SAGB) Late port infection: 1 (SAGB)	No mortality Conversion rate from lap to open surgery: 3/158 (2%) Overall re-op rate approx 7% Median BMI decreased from 44 kg/m^2 pre-op to 1 y: 34 kg/m^2 2 y: 30 kg/m^2 3 y: 28 kg/m^2 Post-op weights: not reported	Authors state adjustable gastric banding operations meet the criteria of a low-risk laparoscopic alternative in the treatment of obesity. The method is difficult to learn but is associated with a lower post-op morbidity. Poor level of scientific evidence. Good long-term follow-up. Although two different bands were used in the surgery the study outcomes are not stated per type of band used.

Table 1 Studies of laparoscopic adjustable gastric band surgery (cont'd)

Author(s) Year/Study duration Type of publication Objectives Follow-up period	Number of patients (n) Characteristics of participants BMI and/or weight (kg)	Surgery duration Hospital stay (days) Post-operative Complications	Study outcomes	Study comments
Abu-Abeid et al. [1] 1999 Nov '96 – Aug '98 Clinical series To report the results and complications of early and intermediate experience of laparoscopic adjustable silicone gastric banding (LASGB) surgery. Follow-up: x̄ 13 mo (range 1-22)	n=391 All referred patients were scheduled for LASGB without exclusion. Age: x̄ 38.1 y (15-72) BMI: x̄ 43.1 kg/m^2 (range 33-66) Weight: not reported	Surgery duration (x̄): 78 min (range 36-165) Hospital stay (x̄): 1.2 d (range 0-8) There were no peri-operative deaths. Conversions: 4 (gastric injury in 1, inadequate instruments in 3) Intra-operative complications: 5 [bleeding from liver injury (3), pneumothorax (1) and stomach injury (1)]. Re-op: 6 during first 3 post-op days [bleeding trocar site (1), band repositioning (5)].	Available for follow-up: 356 BMI: (x̄) 6 mo: 33.5 kg/m^2 12 mo: 31.9 kg/m^2 18 mo: 29.8 kg/m^2 (no ranges given) **Complications**: (4%) **Major**: Subphrenic abscess: 2 Infected splenic hematoma: 1 Trocar site hernia: 1 **Minor**: Wound infection: 3 Painful port site: 9 **Re-op**: 26 patients early band positioning: 5 late band repositioning: 13 band extraction: 5 bleeding trocar site: 1 port migration: 2 (19 were lap re-op.) Patients with intact bands are followed-up regularly.	Authors conclude that LASGB, correctly performed, is a safe bariatric procedure. The short-to-intermediate-term follow-up shows it to be effective with sustained weight loss. However, much longer follow-up will be necessary before final conclusions can be made. Poor level of scientific evidence, follow-up is too short to make a definitive statement about effectiveness of LASGB.

Table 1 Studies of laparoscopic adjustable gastric band surgery, con't

Author(s) Year/Study duration Type of publication Objectives Follow-up period	Number of patients (n) Characteristics of participants BMI and/or weight (kg)	Surgery duration Hospital stay (days) Post-operative Complications	Study outcomes	Study comments
Fielding, et al. [19] 1999 Jan '96 to Dec '97 Clinical series A report of two surgeons, at a single centre, initial experiences using LAGB. Follow-up 3 mo: n=308 12 mo: n=125 18 mo: n=58	n=335 (22 had previous open surgery with VBG) Outcomes reported for n=308. Indications for surgery were BMI > 35 kg/m^2, full understanding of all possible complications. All patients had a history of previous weight loss attempts Age (median): 41 y (range 14-62) BMI (median): 46.7 kg/m^2 (range 34-86) Weight (median): 138 (range 89-265)	Surgery duration: (median) 71 min (range 30-340) [the more recent surgeries are now completed in 30-40 min] Hospital stay: (median) 1.4 d (0-4) No post-op deaths. Conversion to laparotomy: 3 (all had had previous VBG) Wound infections: 4 Subphrenic collection: 1 Band repositioning: 2 Complications occurring after >30 d: 19 (most common was gastric herniation through the band in 12 patients, all required re-op) Port problems: 5 (required resiting in 3, band removal in 2) Band removals: 5 (reasons were untreatable reflux, spontaneous fundal perforation, intolerance to food restrictions)	BMI: (median) 30 kg/m^2 (at 18 mo) Weight loss: (median) 3 mo: 16 $\pm$ 8.3 kg 12 mo: 37 $\pm$ 10 kg 18 mo: 41 $\pm$ 12 kg All patients required band adjustments of 1-4 mL over the course of their follow-up.	Authors state this study demonstrates that LAGB in the short term is comparable to open techniques in effectiveness but has major advantages over open surgery in terms of morbidity, mortality and minimizing hospital stay. A constant single complication in prior reports is band slippage. Following a change in technique the authors report no slippage in their subsequent 108 patients. Poor level of scientific evidence, very short follow-up in majority of patients (3 mo), many patients lost to follow-up.

Table 1 Studies of laparoscopic adjustable gastric band surgery, con't

Author(s) Year/Study duration Type of publication Objectives Follow-up period	Number of patients (n) Characteristics of participants BMI and/or weight (kg)	Surgery duration Hospital stay (days) Post-operative Complications	Study outcomes	Study comments
Favretti et al. [17] 1998 Sept '93 – Jan '98 To report, using the Bariatric Analysis and Reporting Outcome System (BAROS), the long-term results of gastric restrictive surgery by assessing patients in terms of quality of life and ultimate weight loss. Follow-up: > 18 mo (range 19-55 mo)	n=180 morbidly obese and super-obese patients, 170 available for evaluation. Age: x̄ 38 y (15-65) BMI: x̄ 45.5 kg/m^2 (range 35-60) Breakdown of pre-op BMI: < 35 kg/m^2: n=82 ≥ 35 to ≤ 40 kg/m^2: n=45 > 40 to ≤ 45 kg/m^2: n=30 > 45 kg/m^2: n=13 Pre-op weight:: x̄ 124 (range 92-225)	Surgery duration: x̄ 80 min Hospital stay: x̄ 2-3 d. Conversion rate: 2.8% (converted from lap to open surgery) Major complication rate requiring re-op: 2.6% Early complications: Gastric perforation: 1 Stomach slippage: 1 Late complications: Stomach slippage: 6 Erosion: 1. In 50% of cases the re-intervention was done laparoscopically.	No mortality BMI (implied x̄): 1 y: 37 kg/m^2 2 y: 35 kg/m^2 (cutoff) remained below 35 kg/m^2 thereafter Weight loss (implied x̄): 1 y: 27 kg 2 y: 31 kg 3 y: 34 kg BAROS results: Failure rate was 10% Fair results in 42% Good results in 44% Excellent results in 4%. BAROS appeared to correlate with pre-op BMI, follow-up > 18 mo. BMI <35: 3.6% failure rate BMI >45: 31.0% failure rate.	In addition to indices such as BMI and weight loss, the BAROS may be a useful instrument to evaluate outcomes of gastric restrictive surgery. This study did not specifically state whether the post-op numbers for BMI and weight were median or average values. Poor level of scientific evidence. Good long-term follow-up.

Table 1 Studies of laparoscopic adjustable gastric band surgery, con't

Author(s) Year/Study duration Type of publication Objectives Follow-up period	Number of patients (n) Characteristics of participants BMI and/or weight (kg)	Surgery duration Hospital stay (days) Post-operative Complications	Study outcomes	Study comments
Westling et al. [37] 1998 Apr '94 – Jun '96 Clinical series Follow-up study of silicone adjustable gastric banding surgery patients observed according to a prospective protocol, special emphasis on complications and side-effects. Minimum follow-up period: 22 mo Median: 35 mo (range 22-48 mo)	n=90 consecutive patients Lap: 63 Open: 27 All patients were disabled by their overweight or had serious risk factors for obesity-related complications. None had prior obesity surgery. Pre-op: each had a physical exam, laboratory investigation, analysis of eating behaviour, dietician consult and assessment of compliance. Age: (median) 42 y (range 20-68y) BMI: (median) 43 kg/m^2 (range 34-57) Pre-op weight: (median) 120 (range 84-198)	Median surgery duration **Lap**:165 min (range 110-265) **Open**: 91 min (range 45-160) **Converted**: 170 min (range 65-325) [Rate of conversion from lap to open: 25%] Median post-op hospital stay: **Lap**: 2 d (range 1-4) **Open**: 3 d (range 1-7) **Converted**: 4 d (range 3-7) Early wound dehiscence (1 patient) resulted in a re-suturing of the open surgery incision. Wound infection: 4 (lap:1, open:3, healed rapidly with conventional therapy) Unknown fever: 1 (lap) Esophagitis: 33 Band erosions: 10 (6-lap, 1-open, 3-converted)	Conversion-surgery due to difficult exposure, large left liver lobe, splenic injury. BMI (median): 1 y: 32 kg/m2 (range 24-46) 2 y: 31 kg/m2 (range 20-41) Weight loss: not reported Re-op: 32 patients (35%)	Most common reason for re-op was severe symptomatic esophagitis with or without pouch dilatation (n=14) and band erosion (n=10). Two patients were re-op because of pouch dilatation without esophagitis. Patients in the lap group were particularly prone to re-operations. Because of frequent side effects and serious complications of SAGB, authors state they have stopped using this method as a routine therapy for morbid obesity. Poor level of scientific evidence. Good long-term follow-up.

Re-op = re-operation Lap = laparoscopic surgery Open = Open surgery (laparotomy) VBG = vertical banded gastroplasty
y = years mo = months wk = weeks d = days BMI = body mass index (kg/m^2) *Jovell and Navarro-Rubio, reference [27]

Hell et al. [24] prospectively compared three bariatric procedures; vertical banded gastroplasty (VBG), LAGB and Roux-en-Y gastric bypass. Austrian surgeons conducted the LAGB and VBG surgeries and US surgeons the Roux-en-Y surgery. Patients were classified as morbidly obese using BMI and excess weight measurements. There was a statistically significant difference in excess weight loss in favour of the Roux-en-Y procedure over both VBG and LAGB surgeries. Interestingly, there were no significant differences as regards outcomes of VBG and LAGB, which are both strictly restrictive surgeries. There were no patient selection criteria nor post-surgery BMIs reported. And, although the authors stated that the majority of major medical comorbidities were resolved in their respective series there were no descriptions of the types of morbidity. Without this data comparisons with other series are difficult. The favourable BAROS scores and excess weight loss reported in this study would suggest that morbidly obese patients benefit from bariatric surgery treatment regardless of the procedure used.

DeWit et al. [12] performed a randomized controlled trial to evaluate the efficacy of laparoscopic versus open adjustable silicone gastric banding (ASGB) in patients with morbid obesity. Randomization was done by computer at the Department of Clinical Epidemiology on the day of surgery; stratified for sex and BMI. Time for laparoscopic surgery was significantly longer and more difficult than for open surgery. However, the hospital stay was significantly shorter for the laparoscopic surgery group. There was no difference in weight reduction or BMI in the two groups. Late complications, such as incisional hernia and problems with the access port were not different between the groups. The number of readmissions and overall hospital stay in the first year were significantly higher in the open surgery group. The authors state that the follow-up has been far too short to evaluate the final outcome in terms of weight loss [12]. There was no comment on improvements in patient morbidity.

Doherty et al. [14] compared open and laparoscopic techniques in a prospective investigation of adjustable silicone gastric banding (ASGB) devices for the treatment of severe obesity. The study outlined the ongoing revisions of both laparoscopic bands and surgical techniques (open surgery placement versus laparoscopic placement). Efforts to decrease post-operative morbidity included the change to a laparoscopic procedure instead of open surgery. The result was a notable decrease in wound morbidity, pain and disability. Changes in post-operative patient management, such as not inflating the band until 10 weeks after placement, also decreased adverse effects such as intra-abdominal re-operation. However, due to the high re-operation rate the authors concluded that adjustable gastric banding had not met the standards of an acceptable surgical treatment for morbid obesity. They suggested that more convincing data, such as a markedly decreased re-operation rate, was needed from prospective studies with large numbers of participants equally distributed over

multiple sites. Furthermore, the study method should include a controlled protocol followed for five to ten years [14].

O'Brien et al. [32] prospectively evaluated the LAGB system in a consecutive series of patients. The authors stress that the technique has continued to evolve over the past few years, hence it is inappropriate to draw conclusions about effectiveness until there is an established, consistent technique. There was progressive weight loss four years after the operation though many patients were lost to follow-up. Therefore, it may be inappropriate to generalize and say that all patients would claim continued weight loss; additional follow-up is needed [32].

Miller and Hell [30] looked at the effects, complications and outcomes of laparoscopic adjustable gastric band surgery. They stated that although the laparoscopic surgery method was difficult to learn it was associated with a markedly lower post-operative morbidity. Moreover, the operation is easily reversible and the band adjustable to the patient's needs. This study shows that complication rate inversely correlates with the skill of the surgeon.

The study by Abu-Abeid and Szold [1] outlined early and intermediate results of LAGB surgery. The 351 patients with an intact band system continue to be followed-up and currently report sustained weight loss and acceptable BMI. However, follow-up has been too short to detect more serious, late-onset complications or to judge the success or failure of LAGB surgery.

Fielding et al. [19] reported surgical outcomes in 335 LAGB cases and showed that in the short term the outcomes are comparable to open techniques. However, there are advantages over open surgery in terms of morbidity, mortality, and minimizing hospital stay. A recurring complication noted in prior reports of LAGB surgery was gastric slippage that required repositioning of the band. The authors of this series address the slippage problem by making the pouch much smaller and dissecting the esophagogastric junction so that the band posteriorly is around the esophagus. To create the pouch the stomach was pulled up through the band and then sutured stomach to stomach. Since implementing the change in procedure there were no reports of slippage in the subsequent 108 patients. LAGB is technically demanding and the major determinant of a successful outcome of this technique is laparoscopic experience. Longer follow-up is required in order to show sustained weight loss [19].

Favretti et al. [17] state that outcomes of bariatric procedures should be reported by including parameters such as weight loss, improvement in co-morbidity and quality of life assessment. Although the reported weight loss and decrease in BMI after LAGB surgery was good in this series, authors suggest that parameters other than weight loss and decreases in BMI are needed to measure the success of obesity surgery. A BAROS evaluation showed improvement in co-morbidity and assessment of quality of life. However, in this study the clinical status of

patients' co-morbid conditions was not reported. Of note is the correlation with BAROS and BMI; lower pre-operative BMI correlated with a higher percentage of 'good' or 'excellent' BAROS outcome group scores. Conversely, higher pre-operative BMI correlated with a higher percentage of 'failure' BAROS outcome group scores.

Westling et al. [37] reported that laparoscopic silicone adjustable gastric banding surgery was technically simple, required only a short hospital stay and had few peri-operative complications. However, the number of significant, late-onset complications requiring re-operation was unacceptably high. Moreover, complications from gastric restrictive surgery need emergency or semi--emergency care and cause great demands on the availability of surgical expertise. Authors state that laparoscopic silicone adjustable gastric banding surgery may have limited clinical value, and may not be superior to the classical fixed gastric band. The surgeons in this series choose the current standard of care (Roux-en-Y gastric bypass) for those patients requiring a re-operation and anecdotally reported better weight control than LAGB surgery [37].

Of the nine studies analyzed in Table 1, all reported decreases in BMI, weight loss and/or excess weight loss after LAGB surgery. Therefore, LAGB appears to be an effective restrictive surgical treatment for morbid obesity, based on fair to poor levels of scientific evidence. However, results of a recent prospective comparative study [24] found the current Canadian standard of care (Roux-en-Y gastric bypass) superior to purely restrictive gastric surgeries in percent excess weight loss and improvement in quality of life.

Complications specific to adjustable gastric bands

Chelala et al. [10] and Favretti et al. [18] described complications of the LAGB operative technique and suggested ways to avoid them. Specifically, the physiopathology of pouch dilation was characterized and reasons why some LAGB cases had to be converted from laparoscopy to open surgery were explained.

In both series (n=185, n=260), laparoscopic surgery duration was, on average, 90 minutes and the hospital stay averaged two days. Conversion surgery in the Chelala et al. study occurred in 11 patients (three due to left liver lobe hypertrophy, eight due to difficult and risky dissection, short instruments and incorrect band position). Ten patients had conversion surgery in the Favretti study due to risky peri-gastric dissection (five patients), gastric perforation (two patients), too short instruments (two patients) and bleeding from a retro-gastric vessel (one patient).

Complications that occurred less than 12% of the time included:

- aspiration pneumonia
- band slippage
- rotated access ports
- infection of access port

Re-operation was required in approximately 4% of cases and was due to one or more of the following reasons:

- gastric perforation
- band slippage
- twisted reservoir
- irreversible food intolerance that resulted in pouch dilation
- band replacement due to leakage of band or psychological reasons
- recurrent heartburn/esophagitis

Forsell et al. [20] used open surgery to apply adjustable gastric bands. The objective of the study was to describe complications specific to adjustable gastric bands. The key factors in avoiding complications were shown to be the operating technique and the post-operative follow-up. In addition, if during the first month of the post-operative phase the gastric band is left unfilled and the patient's diet is restricted to liquids, the risk of early band dislocation is reduced. In this series most cases of band migration-erosion was evident two to three years after surgery. Possible causes of band migration were rapid- or over-filling of the band. Interestingly, when patients (n=166) were followed-up in the obesity clinic and their band injections were given by residents and nurses the rate of migration of the band was 7.7%. If the patient (n=160) follow-up and injections were done by senior surgeons the rate of migration of the band was 0.6%. The higher percentage of band migration in the former group was attributed to overfilling of the band [20].

Of note is the range of time over which complications occurred; 3 months to 3 years. It is evident that a longer follow-up is needed to establish the role of LAGB surgery for the treatment of morbid obesity [10, 18].

GENERAL CONSIDERATIONS FOR BARIATRIC SURGERY

The following sections will highlight general considerations for bariatric surgery. Information pertaining to patient selection, surgeon training and patient follow-up would be the same regardless of the type of bariatric surgery performed.

Patient selection criteria

It is generally accepted that clinically severe obesity requires operative treatment if non-surgical methods have failed. Criteria such as either of the following can be used as a guide for patient selection [2, 3, 4, 23, 31]:

- BMI > 40 kg/m^2, or > 45 kg above ideal body weight (according to Metropolitan Life weight tables), or,
- Patients with BMI > 35-40 kg/m^2 with serious co-morbidities that require weight reduction with concomitant risks.

Additionally [2, 31]:

- obesity has been present for at least 5 years
- there is no history of alcoholism or major psychiatric disorders
- patient must be between 18 and 65 years of age.

Obese patients in whom adjustable gastric banding surgery is contraindicated are those with gastro-esophageal reflux pre-operatively, those on non-steroidal anti-inflammatory drugs and other mucosal irritating drugs [37].

A Health Technology Assessment information paper prepared by the Department of Hospital Care in Germany reported similar bariatric surgery patient selection criteria. The paper dealt with patient reimbursement claims for LAGB surgery and also included a list of contraindications for LAGB surgery and a questionnaire used by the Sickness Fund Physicians to assess suitability of their patients for LAGB surgery. Highlights from the information paper along with the questionnaire are included in Appendices C and D, respectively.

Training in bariatric surgery

According to the International Federation for the Surgery of Obesity, the Society of American Gastrointestinal Endoscopic Surgeons and the American Society of Bariatric Surgeons [3, 4, 26, 33] the bariatric surgeon should be knowledgeable in all phases of care of severely obese patients. The minimum requirement includes full training in an accredited general or gastrointestinal surgical program. Most bariatric surgeries can be performed with laparoscopic techniques, although very advanced laparoscopic skills are needed. Moreover, extensive experience in the management of clinically severe obesity is essential. Physicians new to the field should have completed a preceptorship in all aspects of the surgery with an experienced bariatric surgeon. A well-trained operating team familiar with the

instruments, equipment and technique is essential. The bariatric surgeon should be committed to:

- continuing medical education courses,
- membership in bariatric surgery societies,
- current updates in the medical literature,
- life-long care of the severely obese patient.

Belachew et al. [6] reported a high rate of late-occurring complications during their early phase of LAGB surgery. After several technical modifications were introduced into the surgical protocol the complication rate dropped considerably. Superb training in both bariatric surgical techniques as well as laparoscopy is crucial to the success of the surgery.

Post-operative care

The desired outcomes of morbid obesity surgery are sustained weight loss and improvement in co-morbidities [11, 33]. Therefore, long-term follow-up is essential in determining whether LAGB surgery has been successful. During the peri-operative period the surgeon should have adequate support in the form of other medical specialists such as cardiologists, pulmonary and infections disease specialists as well as nephrologists, endocrinologists and internists. The anaesthesia department also plays a crucial role in the care program for the clinically severe obese patient both during the operation and in the immediate post-operative period [3, 33]. In the context of Alberta, this would suggest a need for availability of general medical specialty expertise on site in the hospital with sub-specialty expertise available in tertiary level referral centres (Nohr, personal communication).

Long-term follow-up care, as identified by the American Society of Bariatric Surgeons (ASBS) and the American Association of Clinical Endocrinologists, includes: [3, 31, 33]

- office visits during the immediate post-operative period, followed by visits at variable intervals for life
- office visits should include a detailed history, physical examination, laboratory tests tailored to monitor the patient's morbidity
- dietary advice
- behavioural modification techniques (counseling, behavior therapy, setting positive, achievable patient goals, motivational aids such as diaries and daily logs)
- exercise programs
- support group sessions

A National Support Group Network committee has been established by the Allied Health Sciences Section of the ASBS to share information and resources related to care and follow-up of patients who have undergone bariatric surgery [33]. It is essential that the follow-up team obtain satisfactory patient compliance in order to ensure sustained weight loss. Therefore, the first year after obesity surgery must be dedicated to adopting new lifelong habits in order to sustain weight loss [11]. Another important goal of bariatric surgery for morbid obesity is an improvement or resolution of co-morbidities. Since morbid obesity affects many organ systems there should be established definitions of specific obesity-related problems along with a classification of severity [33].

STANDARD OF CARE

Obesity is recognized as an independent risk factor for increased mortality [15]. A realistic estimate of $2 billion per year is the direct cost of obesity to Canada, which corresponds to 2.4% of the total health care budget. There is acceptance by the medical community that obesity is a disease with consequent increased morbidity and mortality that requires surgical intervention when all other attempts at weight loss have failed [15, 16, 28].

Guidelines for the treatment of morbid obesity

Both the Canadian Task Force on the Periodic Health Exam and the National Institutes of Health Consensus Development Conference on Gastrointestinal Surgery for Severe Obesity [15, 23] recommended that:

- First time therapies for severe obesity should include a non-surgical program with integrated components such as diet, exercise and behavioral modification and support.
- Surgical gastric restriction or bypass procedures may be considered for knowledgeable and motivated patients with acceptable operative risks.
- Surgery patients should be evaluated by a multidisciplinary team with medical, surgical, psychiatric and nutritional expertise.
- Surgeons performing the operation should have substantial experience with the appropriate procedures along with adequate support for all aspects of management and assessment.
- Medical surveillance after the surgical therapy is a lifelong commitment.

Non-surgical treatments include low calorie diet, behavioral modification, exercise, and drug therapy. The co-morbidity associated with obesity should be medically treated [23]. However, there has been limited success achieved by these methods; the major failing is the lack of sustained reduced body weight [23]. Thus, for those unresponsive to non-surgical methods of weight control surgical methods that reduce caloric intake/absorption were developed as treatment for clinically severe obesity. The two procedures that dominated practice in the early 1990's were the gastric bypass and vertical banded gastroplasty [7, 23, 29].

Gastric bypass

The gastric bypass is considered the gold standard for the treatment of morbid obesity. This operation limits gastric reservoir capacity by the creation of a 15-mL stapled gastric pouch. However, the stapled pouch is connected by a 10-mm anastomosis to a 40-cm Roux-en-Y jejunal limb, thus bypassing the distal stomach, duodenum, and very proximal jejunum. In other gastric bypass surgery protocols the Roux-en-Y limb is 75 cm and 150 cm in super obese patients (Doherty, personal communication).

This operation combines gastric restriction with emptying of semisolid gastric contents into the jejunum, which seems to exert further additional limitation of food intake. For about 20% of patients, ingestion of simple carbohydrates will result in the dumping syndrome, which will elicit its own control on eating behavior [7]. The dumping syndrome displays symptoms such as lightheadedness, sweating, palpitations, abdominal cramping and diarrhea [2].

Vertical banded gastroplasty

The vertical banded gastroplasty procedure is designed to restrict food intake by limiting gastric volume. A 15-mL gastric reservoir is created by one of several stapling techniques. The small gastric reservoir empties through a narrow channel on the lesser curvature of the stomach to the residual stomach. The channel is reinforced with prosthetic material so as to ensure a channel circumference of 4.5 cm to 5 cm. This operation is attractive because it preserves gastroduodenal continuity and avoids the potential for micronutrient (vitamins and minerals) deficiency [7]. However, it tends to fail in 'sweet-eaters' that adapt to their reduced intake by snacking frequently on soft or liquid foods high in sugar [2].

Complications

In general, the mortality from bariatric surgery in experienced centres is about 1.5% or less [2, 7]. Complications increase proportionately with the severity of patient co-morbidity. Common early complications include the intra-operative incidents such injury to the spleen, stapling the nasogastric tube into the anastomosis, incorrect anastomotic connections and injury to the oesophagus [2]. During the early post-operative period, anastomotic leaks or infections in the left upper quadrant are the most serious complications. If these events are untreatable with percutaneous drainage or other modalities, then prompt exploratory laparotomy should be considered (Nohr, personal communication). Other complications are the same as those with any general abdominal surgery; wound infections, dehiscence, ileus, cardiopulmonary failure, pulmonary embolus, pneumonia and myocardial infarction. Associated with rapid post-operative weight loss is a high rate (10-50%) of cholelithiasis in the form of cholesterol gallstones [2, 7].

Long term patient follow-up is essential. If weight loss is rapid and unsupervised patients will be at risk for macronutrient (fats, proteins, carbohydrates) and micronutrient deficiencies. Low blood levels of iron and vitamin B_{12} occur in 36% to 70% of patients, while low folate levels occur in about 30% to 45%. Actual clinical deficiency states associated with these micronutrients are much less common (12% to 25%). There are less micronutrient abnormalities associated with vertical banded gastroplasty because of gastric and duodenal continuity [7].

FUTURE RESEARCH

Future research into the efficacy and safety of LAGB should address two questions [37]:

- Can a subgroup of obese patients be identified in whom this method could be employed as an alternative to standard of care?
- If such a subgroup is identified, can these individuals be identified pre-operatively?

Studies should also include outcomes such as weight loss, improvement in co-morbidity and quality of life assessment [17].

The Canadian Task Force on Preventive Health Care in their update on the detection, prevention and treatment of obesity found that, in general, the greatest amount of weight loss in the morbidly obese population occurred with surgical therapy rather than dietary or drug treatments. They suggested that further research priorities identify [15]:

- effective primary prevention methods for individual and communities to reduce the prevalence of obesity in the general population.
- long-term effectiveness of weight-reduction interventions using well-designed clinical trials that use predetermined criteria of successful outcomes.
- whether weight-reduction methods are effective in reducing the incidence of major clinical outcomes (examples being myocardial infarction, stroke and cardiovascular death).

CONCLUSION

The clinical studies evaluated for this report took place within a hospital setting. Therefore, whether LAGB surgery can be offered to the morbidly obese population outside a hospital setting cannot be determined at this time.

As with any new surgical technique there will be an obvious learning curve. This was depicted in the early attempts at LAGB surgery. They showed high complication and reoperation rates. Advanced laparoscopic and bariatric surgical skills, along with patient compliance to follow-up instructions, are essential in order to achieve successful outcomes such as decrease in BMI, high percentage of excess weight loss and subsequent decreases in morbidity. Whether LAGB surgery will replace current standard of care or become part of mainstream treatment for morbid obesity will only be determined by well designed studies with greater than five year outcomes of patients who have had the procedure.

APPENDIX A: METHODOLOGY

Literature searches of the databases in the table below were made using the terms shown. The first search included the MEDLINE, HealthSTAR, EMBASE; Dissertation Abstracts and Current Contents databases using the Dialog Corporation, OneSearch® option. This search was restricted to terms in the title or descriptor field. The second search, on CINAHL, was accessed through OVID Technologies. The Cochrane Library was also searched, and several searches were run on the Internet using a variety of terms. With the exception of the Cochrane Library and Internet searches, the literature searches were restricted to the period 1993 - August 1999. The indices from the Obesity Surgery journal (1998-1999) were scanned for relevant articles.

Database Searched *	Subject Headings	Textwords
MEDLINE (1993-1999)	MESH: Exp *obesity, morbid Exp gastroplasty Exp surgical procedures, laparoscopic Subheadings: Classification, complications, diet therapy, drug therapy, diagnosis, economics, epidemiology, prevention and control, rehabilitation, surgery, therapy	
PreMEDLINE Up to Dec 1999		gastric banding morbid obesity
EMBASE 1993-1999	Gastric banding morbid obesity Subheadings: Same as MEDLINE search	
Best Evidence		obesity
HTA		obesity
EED		
DARE		
Cochrane Database of Systematic Reviews		(obesity next surgery)
HealthSTAR	Obesity, morbid	
CMA Practice Guidelines-CPG Infobase		obesity
National Guideline Clearinghouse		morbid obesity
Other: Scanning table of contents of the journal "Obesity Surgery" 1997-1999		

*Database selection is based upon subject matter and time constraints.

- **Date Limits: 1993-2000 except the table of content scanning**
- **Publication type limit to: no limit as per request.**
- **Age Limit: implied adults**

Publication types and number of studies found (Table 1):

- Randomized controlled clinical trials 1
- Controlled clinical trials 0
- Non-controlled clinical trials 7
- Multicentre studies 0
- Prospective comparative studies 1
- Retrospective studies 0

The Health Protection Branch in Canada and the Food and Drug Administration (FDA) in the U.S. were contacted with respect to regulatory approval for the laparoscopic adjustable gastric band.

Single case reports and animal studies were excluded. Studies were included if they had a follow-up of greater than one year and patient numbers greater than 20. Studies were assessed using criteria published by the American Society for Bariatric Surgery (see Appendix B). They define 'Good long-term follow-up', as an average of 2 years; 'ideal long-term follow-up' as 5 years or longer [5]. Studies were evaluated as having 'good, fair or poor' levels of evidence according to levels of scientific evidence outlined by Jovell and Navarro-Rubio [27].

Jovell and Navarro-Rubio published a classification scheme that comments on quality of evidence. Assignment to categories is dependent on conditions of scientific rigour. This scheme forms the basis of the classification of studies in Table 2 into the following categories:

Good:	Meta-analysis of randomized controlled trials (RCTs) or from large sample RCTs;
Good to Fair:	Small sample RCTs and non-randomized controlled prospective trials;
Fair:	Non-randomized controlled retrospective trials, cohort studies and case-control studies;
Poor:	Non-controlled clinical series and various other approaches.

In this health technology assessment:

Efficacy refers to the performance of a technology under 'ideal' conditions or conditions of best practice; and

Effectiveness refers to the performance of a technology under 'routine' conditions. For example when it has become widely distributed in a health care system.

APPENDIX B: GUIDELINES FOR REPORTING RESULTS IN BARIATRIC SURGERY

The American Society for Bariatric Surgery has published "Guidelines for Reporting Results in Bariatric Surgery" [5]. They are reproduced here:

- Utilization of the metric system is strongly recommended.
- Use body mass index (BMI) for the classification of obesity.
- When possible, outcomes of the surgery should be defined in various subgroups stratified for gender, age, ethnicity, socioeconomic status, co-morbidity, and fat distribution (suggested at the NIH Consensus Conference [23]).
- Use measures of fat distribution to identify other health risk factors (e.g. waist-to-hip ratio).
- Analyze separately patients with previous surgery for obesity, those requiring operations, and modification of technique.
- Re-operations should be stated clearly as a percentage in the total series along with reasons for re-intervention.
- Mention the number/percentage of patients lost to follow-up for each time period, and specify how those patients are accounted for in the outcome analysis.
- Ideal long-term follow-up for weight loss should be 5 years or longer. Reporting weight loss with less than 2 years of follow-up is discouraged.
- Percentage of excess weight lost and reduction in BMI are the preferred means in reporting weight loss. Avoid using pounds or kilograms exclusively.

Appendix C: Department of Hospital Care (Medizinischer Dienst der Krankenkassen)

(Hessen, Germany)

Policy advice - Germany

In Germany, the MDK-Hessen (Medizinischer Dienst der Krankenkassen), Department of Hospital Care developed a Health Technology Assessment information paper that dealt with patient claims for reimbursement of LAGB by public health insurance (www.mdk.hessen.de/). The MDK describes adjustable gastric banding as a new technology in which long-term results are still lacking even though the technology is diffusing rapidly. There is a high patient demand for this surgery.

The advice that the MDK gave to physicians included patient selection criteria. In order to have LAGB the following five criteria can be used as a guide:

- BMI > 40 kg/m^2, or 45 kg over ideal body weight
- Patient has been morbidly obese for longer than 5 years
- Repeated attempts at weight loss under a physician's control (1 year minimum)
- Must have obesity-related disease
- Cooperation/willingness of the patient

As well, patients should be informed that there might be additional operations required after LAGB due to excess skin.

The MDK also identified contraindications for LAGB surgery and they included:

- BMI < 35 kg/m^2
- Obesity due to eating sweets or drinking soft drinks
- Age < 18 years or > 60 years
- Alcohol and/or drug abuse
- Patient displays no self-discipline
- Psychiatric diseases
- Patient has disease of the upper gastro-intestinal tract
- Patient has infectious disease
- Patient has had prior operations of the stomach or esophagus
- Must consider general contraindications for elective surgeries (e.g. unable to undergo general anesthesia)
- Pregnancy

If the patient seeks reimbursement for gastric banding by public health insurance, his or her case is reviewed by "Sickness Fund Physicians" (physicians giving advice to the mandatory health insurance plan) either by extensive chart review or a personal visit comprising a physical examination. However, the procedure is also available at private clinics that have their own set of patient selection criteria. In this case the patient has to pay for the procedure unless covered by a private insurance plan. See Appendix C for information regarding the questionnaire used by the Sickness Fund Physicians to assess suitability of their patients for LAGB surgery.

APPENDIX D: ELIGIBILITY FOR SURGERY QUESTIONNAIRE

This questionnaire was developed for use by the Sickness Fund Physicians to assess suitability of their patients for LAGB surgery. It was written in the German language, following is an English language précis. This standardized questionnaire is intended to aid the physician to determine the justification for LAGB surgery. It does not provide a 'yes or no' answer, rather it acts as a guide. Patients must be judged if they are suitable on a case-by-case basis by their physicians.

GENERAL INFORMATION:

Name Age Weight Height

Number of years you have suffered with clinically morbid obesity

DIETING ATTEMPTS:

Describe types of diet(s) you have tried to lose weight.

Did you lose weight on a diet?

How fast did you regain the weight you had lost?

What was the reason for stopping the diet?

LAGB SURGERY:

How did you hear about LAGB surgery?

What is your weight loss goal?

Have you ever participated in obesity counselling?

Do you feel that your obesity leads to problems with other people?

EATING HABITS:

How many meals do you eat a day?

Do you eat between meals?

What types of sweets do you eat?

What is your favourite food/dish?

How often do you eat this food/dish per week?

Describe what you ate last Sunday?

Do you feel of satisfied after a meal?

STATE OF HEALTH:

Do you have chronic diseases of

- Heart?
- Circulation?
- Lungs?
- Orthopedic diseases of spine and/or joints?

Are you currently under treatment for neurological or psychiatric diseases?

Have you had cancer?

- When?

Do you suffer from reflux?

Have you had esophagitis?

Have you had:

- Inflammation of the gastric tissues (gastritis)?
- Stomach or intestinal ulcers?
- Prior operations for g.i. tract?
  - ➢ Explain

Do you take drugs on a frequent basis?

- Which ones and how often?

Are you on cortisone?

- Do you take on a frequent basis?
- How often and how much (dose/frequency)?

Who will look after you after your LAGB surgery?

Who will be your obesity counsellor?

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